Drug Utilization Review Board

Meeting Minutes

Thursday, September 13, 2018
7:15 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

Board Members Present:
Jennifer Brinton, MD
Eric Cannon, PharmD, FAMCP
Neal Catalano, PharmD
Aesha Drozdowski, PharmD
Steve Lore, MD
Kim Michelson, DDS
Kumar Shah, MSc, Peng, Board Chair
Susan Siegfreid, MD
Katherine Smith, PharmD
Sharon Weinstein, MD

Department Staff Present:
Jennifer Strohecker, PharmD
Robyn Seely, PharmD
Bryan Larson, PharmD
Joe Busby, RPh, MBA
Merelynn Berrett, RN
Heather Santacruz, RN

University of Utah Drug Regimen Review Center Staff Presenter:
Valarie Gonzales, PharmD

Other Individuals Present:
Elena Martinez Alonso, U of U
Jeff Mussack, Otsuka
Rick Kegler, Otsuka
Linda Wilson, Biogen
Erika Devlin, Sarepta
Lisa Borland, Sarepta
Cheryl Donahue, Sarepta
Kara Clawson, Sarepta
Jessie Graff, Roseman
Deron Bothe, Teva
Lauren Heath, U of U
Rhonda Clark, Indivior
Griffin Loutzahuser, U of U
Don McCaffrey, Vertex
Albert Lin, U of U
Michael Faithe, Amgen
An Vo, Roseman
Lori Howarth, Bayer
Rob Booth, Allergan

Meeting conducted by: Kumar Shah

1. **Welcome & Housekeeping:** Kumar Shah opened the meeting. Robyn Seely asked the Board if they would like to continue to start meetings at 7:15am, or move the start time to 7:00am. The Board members present (Catalano, Drozdowski, Michelson, Shah, and Siegfreid; the others arrived later) drew no conclusion. Robyn Seely stated that the decision was not substantive Board business and could be discussed via email, and that she could therefore poll the Board via email and let them know of the results at the next meeting.

2. **Review and Approval of July Minutes:** Neal Catalano made a motion to approve the July minutes. Kim Michelson seconded the motion. All in favor; motion passed.

3. **Pharmacy and Therapeutics Committee Report:** Bryan Larson reported that the P&T Committee did not meet in August and will be reviewing hemophilia factor IX and combination

factor VIII/Von Willebrand factors next week.

4. **Aimovig (erenumab for the prevention of migraine headaches)**

   a. **Information:**
   Robyn Seely presented recommended prior authorization (PA) criteria for this new drug. The drug is the first in its class, a monthly prophylactic subcutaneous injection.

   b. **Board Discussion and Public Comment:**
      1. **Michael Faithe (Amgen)** spoke for his allotted three minutes, after which Board members asked him questions. Kumar Shah asked about adverse effects and Michael directed him to the prescribing information.
      2. Eric Cannon raised caution regarding the higher dose. The recommended dose of Aimovig is 70mg once monthly, but the prescribing information states that "some patients may benefit from a dosage of 140mg" once monthly. Patients and prescribers must remember that higher doses aren't necessarily better. Eric suggested that there be PA criteria to limit dosing. Kim Michelson suggested leaving dosing to provider discretion.
      3. Sharon Weinstein educated the Board regarding migraine pain studies. Migraine pain is quantified differently than all other pain; in Headache Days per Month. Sharon and Aesha Drozdowski conversed about the subjective nature of pain and the calculation in reduction of pain. Michael Faithe briefly reviewed the studies in the prescribing information
      4. Neal Catalano noted that the PA criteria as presented required a "trial and failure of at least two of the following drugs: amitriptyline, gabapentin, propranolol, topiramate, and valproate." This list includes drugs that are not FDA-approved to treat migraines. Robyn Seely responded that those drugs were included in best practice migraine treatment guidelines. Sharon Weinstein observed that, if we want to follow guidelines, this list is incomplete. The Board discussed differences between guidelines and FDA-approved treatments.

   c. **Board Action**
   The Board generally agreed that Robyn Seely should research the most recent guidelines, with the intent to require trial and failure on a few before approval of Aimovig, and bring a new version of the PA criteria to the Board next month.
      1. Motion: Neal Catalano. Second: Katherine Smith. All in favor, Motion passed

5. **Exondys 51 (eteplirsen for the treatment of Duchenne muscular dystrophy)**

   a. **Information:**
   Robyn Seely presented a change to the existing prior authorization (PA) criteria for this drug.

   b. Board Discussion and Comments
      1. **Kelly Maynard of the Little Hercules Foundation** had asked to be on the agenda, but had been unable to come to the meeting and had not submitted a

letter or other materials for the Board's consideration

2. **Russell Butterfield, M.D. of Primary Children's Hospital** spoke for a moment, introducing himself and then offering his expertise as invited as the discussion continued. His practice is the regional Center of Excellence for the treatment of Duchenne muscular dystrophy (DMD), participating in the FDA's Exondys 51 trials, and prescribing Exondys 51.
3. **Lisa Borland, Sarepta** introduced herself and made herself available for questions.
4. **Sarepta, the manufacturer of Exondys 51 also sent a written letter**, which was read aloud to the Board and is available upon request.
5. **The Parent Project, Muscular Dystrophy sent a written letter** which was read aloud to the Board and is available upon request.

6. **Hemlibra (emicizumab for prophylactic treatment of hemophilia A)**
   a. Time did not allow for this topic to be presented or discussed, it will be presented at the next meeting, Thursday October 11th, 2018.

7. **Adjournment:** Kim Mickelson made a motion to adjourn. Eric Cannon seconded the motion. All in favor; meeting adjourned.

Audio recordings of DUR meetings are available online at: https://medicaid.utah.gov/pharmacy/drug-utilization-review-board?p=DUR%20Board%20Audio%20Recordings/